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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,598	11/30/1998	LOUIS DELESALLE	065691/0145	3390

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/07/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/194,598

Applicant(s)

DELESALLE ET AL

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 27.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 12 February 2003 has been entered.
2. Applicant's attorney, Stephen B. Maebius, confirmed by telephone on 22 April 2003, that Applicant had intended entry of the amendment after the final rejection filed 12 September 2002 as Paper No. 23. The Amendment filed 12 February 2003 amends claims 12 and 18 from those amendments presented in Paper No. 23, filed 12 September 2002. The Examiner has entered Paper No. 23, and claims 13, 14 and 19 have been cancelled without prejudice as requested. Applicant is required to confirm, in response to this Office action, Applicant's intent to enter Paper No. 23 upon filing of a Request for Continued Examination under 37 CFR § 1.114.

Status of the Application

3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

5. Claims 12, 15, 16, 17 and 18 are objected to because of the following informalities:

At claims 12, line 2 and 18, line 4, the phrase "borne by" is awkward and should read -- comprising -- or -- consisting of --.

Claim 15 lacks an article of language and should read -- A recombinant --, and at line 2 the phrase "a recombinant" should read -- the recombinant -- in referring to claim 12.

Claim 16 is confusing and should read -- A plant cell comprising the recombinant plant cytoplasm of claim 15 --.

At claim 17, the phrase "A plant cell" should read -- The plant cell -- in referring to claim 16.

Appropriate correction is required.

6. Claim 15 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 fails to further limit claim 12 because claim 15 is directed to a different product that is broader in scope than claim 12.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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8. Claims 12 and 15-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 12, lines 2-3 and claim 18, line 4, the phrase "a sunflower orf 522 sequence" is indefinite because it is unclear from the instant specification that there is more than one sunflower orf 522 given the teachings of the specification, hence it is unclear what the metes and bounds of the claims are.

At claim 15, the use of the term "genome" renders the claim indefinite because the specification defines "genome" as either the nuclear or mitochondrial type (page 2, lines 28-29). Hence, it is unclear what the metes and bounds of the claimed recombinant plant cytoplasm are.

Claims 16 and 17 are indefinite because they do not obviate the indefiniteness of claim 15.

At claim 18, lines 1 and 2, the phrase "the chicory genus" is indefinite because it is unclear what the metes and bounds of this limitation are. The term "chicory" is used as a common name for a plant of the species *Cichorium intybus*, and does not denote a genus designation. Applicant's use of said phrase appears to be repugnant to the accepted meaning known in the art at the time of Applicant's invention.

9. Claims 12 and 15-18 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is

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repeated for the reason of record as set forth in the last Office action mailed 14 January 2002.

Applicant's remarks filed 12 February 2003 do not specifically argue the error of the Examiner's rejection of the instant claims for lack of adequate written description. Applicant states that Applicant has amended pending claims 12 and 18 to be directed to chicory plants or to a male sterility conferring sequence with at least 90% homology to the sunflower orf 522 sequence (page 2, 3rd paragraph of the Remarks). The Examiner does not consider this an argument, only a statement of Applicant's actions.

The use of the phrase "90% homology" denotes a evolutionary relationship between the nucleotide sequence conferring male sterility and the sunflower orf 522 (see Reeck *et al* 1987, Cell 50:667). To this point, Applicant has failed to adequately describe the genus of nucleotide sequences having 90% homology to the sunflower orf 522 that confers male sterility. If the said phrase is read as "similarity" or "identity", again, Applicant has failed to adequately describe the genus of nucleotide sequences having 90% similarity or identity to the sunflower orf 522. Applicant only describes using a commercially available *Helianthus annuus* that has cytoplasmic male-sterility due to the presence of the male-sterile conferring orf 522 nucleotide sequence (page 5, lines 9-11 of the specification). Applicant does not describe any sequences having 90% homology, similarity or identity to the sunflower orf 522 that confers male sterility.

See *In re Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the

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invention and reference to a potential method of isolating it; what is required is a description of the DNA itself".

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

10. Claims 12 and 15-18 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a male sterile 'chicory' plant comprising the sunflower orf 522 sequence wherein said sequence confers male sterility and said plant is produced by protoplast fusion between a sunflower protoplast comprising said sequence and a 'chicory' protoplast, does not reasonably provide enablement for any recombinant plant genome comprising a male-sterility conferring sequence with at least 90% homology to the sunflower orf 522 sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 14 January 2002. Applicant's arguments filed 12 February 2003 have been fully considered but they are not persuasive.

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Applicant argues that one of ordinary skill in the art does not have to engage in undue experimentation to practice the claimed invention. This argument is not found to be persuasive because Applicant provides no guidance how to make and use a nucleotide sequence conferring male sterility with at least 90% homology with the sunflower orf 522 sequence in the instant specification.

See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

Claim Rejections - 35 USC § 102

11. Claims 12 and 15-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rambaud *et al* (1993), taken with the evidence of Dubreucq *et al* (1999, Theoretical and Applied Genetics 99:1094-1105).

Rambaud discloses a method of making the recombinant chicory plant (*Chichorium intybus* L.) genome CT41/1 comprising at least one chicory gene and a nucleotide sequence conferring male sterility borne by the sunflower orf 522 sequence,

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said sunflower orf 522 sequence inherently comprises polynucleotide sequences having the sequence shown in SEQ ID NOs: 1 and 2 (see page 348, left column). Dubreucq discloses evidence that the genome of the cybrid CT41/1 (syn. cytotype 411) comprises the sunflower orf 522 (see Table 2 on page 1099). Hence, Rambaud has previously disclosed all of the claim limitations.

See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method. In the instant case, Rambaud discloses the method step of integrating into a cell genome of a chicory plant a nucleotide sequence conferring male sterility bone by a sunflower orf 522 sequence (page 348, left column, 1st-4th paragraphs).

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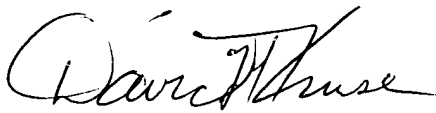
Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.


DH 1638

David H. Kruse, Ph.D.
2 May 2003